

**Remarks/Arguments:**

**Rejection Under 35 U.S.C. §112**

Claims 70 and 71 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 70 is hereby amended into independent form and does not include the limitations of claim 69 which were added in the last amendment. It is respectfully submitted that claims 70 and 71 as amended are fully supported by the original specification. Since no prior art has been cited against these claims, it is respectfully submitted that claims 70 and 71 are in condition for allowance.

**Rejection Under 35 U.S.C. §102(e) and 103(a)**

Claims 61, 62, 64-66 and 68 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,488,673 (Laufer et al.). Claims 63, 69 and 73 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Laufer et al. in view of U.S. Patent No. 5,913,884 (Trauner et al.). Applicants respectfully traverse these rejections.

Anticipation requires that each and every limitation of the claim be disclosed, either expressly or under principles of inherency, in a single prior art reference. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Absence from the reference of any claimed limitation negates anticipation. *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

"To establish a *prima facie* case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 61 recites:

"A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue."

The Office Action indicates on page 3 that "Laufer et al. disclose a method of applying light energy to the inner wall of a vessel via a light delivery catheter without occluding fluid flow ... after applying a photo-activatable agent (a psoralen agent injected intravenously) to the vessel and which is necessarily taken up by the wall and the adventitial area of the vessel (as disclosed by the applicant's specification). . . ." (emphasis added).

The Final Office Action acknowledges that Laufer et al. teaches applying light energy to the inner wall. The Final Office Action does not include a basis in fact and/or technical reasoning to reasonably support that applying light energy to the inner wall necessarily is taken up by the adventitial area of the tissue.

As set forth in M.P.E.P. §2112, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In Ex parte Levy, the Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

Trauner et al. explains at column 2, lines 27-29, that "the modulation can include inhibiting fibrosis by administering a high dose of photodynamic therapy." (emphasis added). As explained at column 2, line 60 to column 3, line 3,

[a]s used herein, 'low dose' photodynamic therapy means a dose sufficient to kill from 0% to about 10% of all cells exposed to the photoactiviting light if the photosensitizer is untargeted, or from 0% to about 10% of the targeted cells exposed to the photoactiviting light, if the photosensitizer is targeted. As used herein, 'high dose' photodynamic therapy means a dose sufficient to kill from about 10% to about 90% of all cells exposed to the photoactivating light if the photosensitizer is untargeted, or from about 10% to about 90% of the targeted cells exposed to the photoactivating light, if the photosensitizer is targeted.

Trauner et al. teaches that a low dose therapy targets only a small percentage of cells, i.e. 10% or less of the cells, and therefore, it is not inherent that the agent would be taken up in the adventitial area nor that such would inherently result in increasing the adventitial area. If a high dose therapy were utilized, such would result in an inhibiting of fibrosis.

Laufer et al. provides no basis against this teaching away of Trauner et al. Taking the complete teachings of the cited prior art references, the suggested applying light energy to an extent necessary to heat from the inside surface to the outer surface, would likely result in inhibition of fibrosis, not "increasing an adventitial area in the area of the target tissue" as recited in claim 61.

Laufer et al. and Trauner et al., alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention, either expressly or inherently. Applicants respectfully submit that claim 61 is in condition for allowance. Claims 62-66 and 68 depend from claim 61 and are allowable for at least the reasons set forth above.

Similar to claim 61, independent claim 69 recites "applying an agent and irradiating a target region of tissue with UVC irradiation to accomplish an interaction between the agent and the UVC irradiation; and inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue. . . ." As explained above, Laufer et al. and Trauner et al., alone or in any reasonable combination, fail to teach or suggest such limitation of the claimed invention, either expressly or inherently. Applicants respectfully submit that claim 69 is in condition for allowance. Claim 73 depends from claim 69 and is allowable for at least the reasons set forth above.

It is respectfully submitted that each of the pending claims is in condition for allowance. Early reconsideration and allowance of each of the pending claims are respectfully requested.

If the Examiner believes a further interview, either personal or telephonic, will advance the prosecution of this matter, the Examiner is invited to contact the undersigned to arrange the same.

Respectfully submitted,



Joshua L. Cohen, Reg. No. 38,040  
Glenn M. Massina, Reg. No. 40,081  
Attorneys for Applicant

JLC/GMM/Ir

Dated: February 25, 2008

Appln. No.: 10/798,786  
Amendment Dated February 25, 2008  
Reply to Office Action of November 26, 2007

BSI-557US1

P.O. Box 980  
Valley Forge, PA 19482  
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.